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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,263	11/28/2001	Phillip Dan Cook	ISIS-4943	3783

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03/26/2003

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EXAMINER

SCHULTZ, JAMES

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Feb

Office Action Summary	Application No. 09/996,263	Applicant(s) COOK ET AL.	
	Examiner J. Douglas Schultz	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7 and 9</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 8 is objected to because of the following informalities: The term "alkoxy" in said claim appears to be misspelled as "alkloxy". Appropriate correction is required.

Information Disclosure Statement

Applicant's original IDS filed February 2, 2002 contains several references that were not considered for the following reasons. Reference "BK" was not considered as it is not in proper format. References "BO" and "FH" were not provided. Reference "GS" is a duplicate. Translations of references "HY", "IR", and "IV" were not provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 8 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention of the above listed claims is drawn to a mixed sequence oligonucleotide or oligonucleotide analog including more than one 2'-modified 2'-deoxyfuranosyl moiety wherein

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said modification comprises substitution by halo, azido, amino, alkoxy, thioalkoxy, alkylamino, alkyl, and wherein one of said 2'-modified 2'-deoxyfuranosyl moieties is different from another of said 2'-modified 2'-deoxyfuranosyl moieties, or wherein one of the two different moieties is alkoxy, which may be methoxy, or an alkyl group which may comprise a straight or branched chain alkyl, wherein said alkyl may contain unsaturation, and said nucleotide sequence that is nuclease resistant.

The lack of a conjunction in Applicant's recital of possible 2'-modifications in claim 8, and by dependency claims 11-13 is problematic, such that a reasonably broad interpretation could include a nucleotide modification comprising substitution by all moieties listed, all covalently attached to one single nucleotide. Applicant has not provided adequate written support for this anywhere in the specification, and such constructs are not known in the art. Insertion of the word "or" before "alkyl" in line 3 of the claim would be remedial. For the purposes of examination, it is assumed that Applicant intended this insertion, particularly in view of Applicant's dependent claims that contain such language.

3. Claims 8-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **new matter** rejection.

Independent claim 8 is relied upon as described above.

Applicants' amendment dated April 19, 2002 adds new claims 8-13 that contain the limitation that the claimed oligo must comprise at least two different 2'-substitutions, wherein said different substitutions are selected from halo, azido, amino, alkoxy, thioalkoxy, alkylamino, and alkyl. However, Applicant has not described any oligonucleotide in the specification as originally filed that meets these criteria. While the specification describes several oligonucleotides comprising two different 2'-substitutions, in all such cases one of the two said substitutions is a 2'-deoxy-erythro-substitution, which is not among the list of claimed substitutions submitted in Applicants' newly submitted claims 8-13. Therefore, Applicant has not disclosed any oligonucleotides that comprise at least two different 2'-substitutions, wherein said different substitutions are selected from halo, azido, amino, alkoxy, thioalkoxy, alkylamino, and alkyl.

Furthermore, nowhere in the specification as originally filed does it teach any oligonucleotides that must comprise at least two different 2'-substitutions. The specification as filed discloses only oligonucleotides that comprise at least one 2'-substitution. While the new matter requiring at least two different 2'-modifications selected from the claimed list is broadly encompassed by the originally filed disclosure, which requires at least one such modification, it does not provide adequate written support for specific oligos that must be comprised of at least two different such modifications selected from halo, azido, amino, alkoxy, thioalkoxy, alkylamino, and alkyl, because such species are not referenced or explicitly disclosed. One of skill in the art would not have envisioned oligonucleotides that comprise at least two different 2' modifications as newly claimed. Therefore, Applicants have not provided adequate written

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support for oligonucleotides that must comprise at least two different 2'-substitutions, wherein said different substitutions are selected from halo, azido, amino, alkoxy, thioalkoxy, alkylamino, and alkyl.

Finally it is noted that Applicants amendment fails to identify where in the specification written support exists for Applicants' amended subject matter. See M.P.E.P. § 714.02, § 2163.06, and § 2163.04. Should Applicant believe that written disclosure is present in the specification as originally filed, Applicants are invited to point out with particularity where in the specification such support may exist. However, in the absence of evidence to the contrary, newly added claims 8-13 are rejected for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Draper et al.

(U.S. Patent Number 5,612,215).

Claims 8-13 have been rejected under 35 U.S.C. § 112 1st paragraph written description as outlined above. In light of said rejection, a priority date is not accorded the present invention, however, the following rejection follows provides Applicant with relevant prior art.

The invention of the above listed claims is drawn to a mixed sequence oligonucleotide or oligonucleotide analog including more than one 2'-modified 2'-deoxyfuranosyl moiety wherein said modification comprises substitution by halo, azido, amino, alkoxy, thioalkoxy, alkylamino, alkyl, and wherein one of said 2'-modified 2'-deoxyfuranosyl moieties is different from another of said 2'-modified 2'-deoxyfuranosyl moieties, or wherein one of the two different moieties is alkoxy, which may be methoxy, or an alkyl group which may comprise a straight or branched chain alkyl, wherein said alkyl may contain unsaturation, and said nucleotide sequence that is nuclease resistant.

The oligos of Draper et al. comprise phosphorothioated nucleotides sequences containing both 2'-O-methyl moieties, and 2'-C-allyl modifications (see claim 20). Accordingly, Draper et al. teaches all the limitations of, and thus anticipates, the invention of the present claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD
March 20, 2003


KAREN LACOURCIERE
PATENT EXAMINER